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Achieve Life Sciences Announces Expansion of Cytisinicline Clinical Operations Team and Granting of Inducement Awards

SEATTLE, WA and VANCOUVER, BC / ACCESSWIRE / August 13, 2021 / Achieve Life Sciences, Inc. (NASDAQ:ACHV), a clinical-stage pharmaceutical company committed to the global development and commercialization of cytisinicline for smoking cessation and nicotine addiction, today announced that the Company has expanded its Clinical Operations Team with the hiring of a Director of Clinical Operations, a Senior Manager of Clinical Trials, and a Senior Director of Biometrics.

"We are excited to welcome our new clinical team members to Achieve and look forward to their contributions to the cytisinicline development program, including their efforts to support our fully enrolled Phase 3 ORCA-2 trial in combustible cigarette cessation and the planned Phase 2 ORCA-V1 trial in nicotine e-cigarette cessation," commented Dr. Cindy Jacobs, Achieve's President and Chief Medical Officer.

Achieve's Board of Directors approved three new employment inducement grants of stock options to purchase an aggregate of 45,000 shares of common stock with grant dates of August 10, 2021, August 23, 2021, and September 13, 2021. Achieve granted the stock options as a material inducement to these employees for entering into employment agreements with Achieve in accordance with Nasdaq Listing Rule 5635(c)(4).

The stock options approved under the Inducement Grants were issued on terms substantially similar to Achieve's 2018 Equity Incentive Plan and have a per share exercise equal to the closing price of Achieve's common stock on the applicable grant date. The stock options vest over four years, with 25% vesting on the first anniversary of the employees' respective start dates and 1/36TH of the remaining shares vesting monthly thereafter, subject to the employees' continued employment on each such date. The stock options have a 10-year term and are subject to the terms and conditions of the stock option agreements.

About Achieve and Cytisinicline

Tobacco use is currently the leading cause of preventable death that is responsible for more than eight million deaths worldwide, and nearly half a million deaths in the U.S. annually.^{[1][2]} More than 87% of lung cancer deaths, 61% of all pulmonary disease deaths, and 32% of all deaths from coronary heart disease are attributable to smoking and exposure to secondhand smoke.² Achieve's focus is to address the global smoking health and nicotine addiction epidemic through the development and commercialization of cytisinicline.

Cytisinicline is a plant-based alkaloid with a high binding affinity to the nicotinic acetylcholine receptor. It is believed to aid in smoking cessation by interacting with nicotine receptors in the brain by reducing the severity of nicotine withdrawal symptoms and by reducing the reward and satisfaction associated with smoking.

Achieve recently announced completion of enrollment in the Phase 3 ORCA-2 clinical trial, evaluating cytisinicline as a treatment for combustible cigarette cessation. Topline results from the ORCA-2 trial are expected in the first half of 2022. For more information on Achieve Life Sciences and cytisinicline please visit www.achievelifesciences.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the timing and nature of cytisinicline clinical development activities, the potential market size and market acceptance for cytisinicline, the potential benefits of cytisinicline and the development and effectiveness of new treatments. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Achieve may not actually achieve its plans or product development goals in a timely manner, if at all, or otherwise carry out its intentions or meet its expectations or projections disclosed in these forward-looking statements. These statements are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described in the forward-looking statements, including, among others, the risk that cytisinicline may not demonstrate the hypothesized or expected benefits; the risk that Achieve may not be able to obtain additional financing to fund the development of cytisinicline; the risk that cytisinicline will not receive regulatory approval or be successfully commercialized; the risk that new developments in the smoking cessation landscape require changes in business strategy or clinical development plans; the risk that Achieve's intellectual property may not be adequately protected; general business and economic conditions; and the other factors described in the risk factors set forth in Achieve's filings with the Securities and Exchange Commission from time to time, including Achieve's Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q. Achieve undertakes no obligation to update the forward-looking statements contained herein or to reflect events or circumstances occurring after the date hereof, other than as may be required by applicable law.

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[1] World Health Organization. WHO Report on the Global Tobacco Epidemic, 2019. Geneva: World Health Organization, 2017.

[2] U.S. Department of Health and Human Services. The Health Consequences of Smoking - 50 Years of Progress. A Report of the Surgeon General, 2014.

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